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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,640	12/08/2000	Anthony J. McHugh	10322/8	2399

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N . 09/733,640	Applicant(s) MCHUGH ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2000 .
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |   |
|---|---|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 20) <input type="checkbox"/> Other: _____ .                                   |

### **DETAILED ACTION**

Claims 1-47 are included in the prosecution of this application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 27 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 27 and 41 are indefinite since they depend on claim 21, which already recites the composition containing a bioactive agent.

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

**Claims 1, 5-7, 9, 14-18, 21, 22, 27-32, 34, 36, and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Tipton et al (5792469).**

Tipton et al disclose biodegradable composition containing poly-caprolactone and poly-(D,L lactide), a biocompatible solvent, and a bioactive agent (Note ex. 2). The reference discloses the method of making the composition (Note Ex. 1-3) and the

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method of inserting the composition into an organism (Note Example 7). It is inherent that Tipton et al's biodegradable film dressing when applied to a wound area as seen in the examples will be sterile before application.

**Claims 1, 2, 4-6, 20, 34, 35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruiz (5980945).**

Ruiz discloses a sustained release drug formulation containing poly-(D,L lactide), a biocompatible solvent (benzyl benzoate), an emulsifying agent, and a bioactive agent. Ruiz discloses the method of making the composition and the method of administering the composition to an organism via an injection. (Note Examples) It is inherent that Ruiz composition would be sterile prior to injecting the composition into an organism.

**Claims 1-5, 8, 20, 34, 35, 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al (6130200).**

Brodbeck et al disclose a gel composition containing a biocompatible polymer, ethyl or benzyl benzoate, a biocompatible component solvent, a bioactive agent, and an emulsifier. (Note Examples, Tables 1-2)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 10-13, 19, 23-26, 33, 37, and 42-47 are rejected under 35**

**U.S.C. 103(a) as being unpatentable over Tipton et al cited above, combined with Brodbeck et al, cited above.**

As set forth above, Tipton et al disclose a poly-caprolactone and poly-(D, L lactide), a bioactive agent, and a biocompatible solvent (NMP). Tipton et al does not teach a biocompatible component solvent, ethyl benzoate as the biocompatible solvent, or an emulsifier.

As set forth above, Brodbeck et al teach a gel composition containing a biocompatible polymer, ethyl benzoate, a biocompatible solvent, an emulsifier, and bioactive agent. Brodbeck et al teach the use of ethyl/benzyl benzoate and a secondary solvent such as NMP. The reference discloses that NMP takes up substantially more water alone than a combination of ethyl/benzyl benzoate and NMP. The decrease in water intake increases the stability of the active agent. (Note Examples 3-4, col. 14, lines 13-55) Brodbeck et al disclose the use of an emulsifier not only to dilute the viscous gel formed by the solvent and the polymer but the emulsifier does not affect the release properties of the system (col. 19, lines 10-20). Further, the reference teaches a kit for administering the composition and the kit allows the agent to be separate from the solvent until its use (col. 7, lines 23-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Tipton et al and Brodbeck et al since both teach biodegradable polymer composition for administering bioactive agents. One would be motivated to do so since Brodbeck et al teaches the advantages of using ethyl

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or benzyl benzoate, using a two solvent system, and an emulsifier in a system such as Tipton et al.

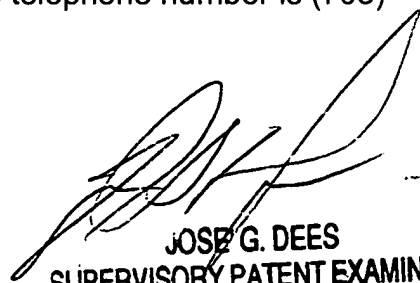
Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Tipton et al and Brodbeck et al as set forth above and administer the composition via a kit as suggested by Brodbeck et al. One would be motivated to do this since the composition would be kept "fresh" as suggested by Brodbeck et al until its use.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616